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Resource Utilization Due to Breakthrough Pain in Patients With Chronic Painful Conditions

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Background

- Breakthrough pain, also referred to as a pain flare, has been defined as "a transitory increase in pain to greater than moderate intensity, which occurs on a baseline pain of moderate intensity or less in a patient receiving chronic opioid therapy"¹
- Limited research has been published to demonstrate the economic impact of pain flares in terms of direct and indirect costs

1. Portenoy RK, Hagen NA. Breakthrough pain: Definition, prevalence, and characteristics. Pain 1990;41:273-81.

Objectives

- Primary:** To capture healthcare resource consumption and work loss in a population of patients with chronic pain who have pain flares from one or more of the following non-cancer conditions:
 - Musculoskeletal problems (back, knee, shoulder, neck, and other areas)
 - Rheumatological diseases (arthritis, lupus, and others)
 - Chronic headache
 - Sickle cell anemia
- Secondary:** To explore the relationship between anxiety, depression, and pain in this population

Study Design

- A 3-month prospective, observational study of outpatients from a large tertiary U.S. medical center

Methods

Eligibility Criteria

- Inclusions**
 - Patients with chronic pain meeting the following definition: "Chronic pain is pain that continues a month or more beyond the usual recovery period for an injury or illness or that goes on for months or years due to a chronic condition. The pain is usually not constant, but can interfere with daily life at all levels."²
 - Age ≥18 years
- Exclusions**
 - Patients who were not able to communicate in English sufficiently well to complete the required follow-up
 - Patients deemed to be inappropriate for participation by their physician

2. American Chronic Pain Association. Definition of Chronic Pain. Available at: <http://www.theacpa.org>

Data Collection

- Participants were recruited through Jefferson University Physicians' practices
 - Jefferson Pain Center
 - Rheumatology
 - Hematology (sickle cell)
 - Neurology
- Data collection tools:
 - Patient diary where healthcare utilization and work loss were captured each day for 7 consecutive days upon study entry
 - Monthly patient survey at months 1, 2, and 3 to capture healthcare utilization, work loss, changes to employment, and/or changes in treatment

Study Measures

- Patient demographics
- Pain score (10 point scale)
- Sleep quality (Pittsburgh Sleep Quality Index)^{*}
- Quality of life (SF-12, v2)^{*}
- Pain Flare Definitions Questionnaire^{*}
- Satisfaction with pain treatment (Pain Flare Treatment Satisfaction Questionnaire)^{*}
- Healthcare utilization due to pain flare(s) or pain treatments:
 - Hospitalizations
 - Outpatient medical visits
 - Phone calls to physician office
 - Emergency room visits
 - Pain medications
 - Alternative treatments for pain
- Work productivity loss due to pain flares or pain treatments (Health-Related Productivity Questionnaire-Diary)
 - Hours of work missed (absenteeism)
 - Impact on work output (presenteeism)
 - Hours of work missed at home ("around the house")

^{*}Results pertaining to these measures are beyond the scope of this abstract

Analysis

- Examined direct medical costs and work productivity by pain source, gender, ethnicity, occupation/employment status, and age
 - Results presented herein are limited to diary findings from the first 161 enrollees (data collection is ongoing)
 - Breakthrough pain was defined as 1 or more pain flares during the diary period
- This analysis was not limited to patients receiving opioids due to small sample size

Disclosure

This study was funded through an investigator sponsored research grant from Cephalon, Inc.

Acknowledgements

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Results

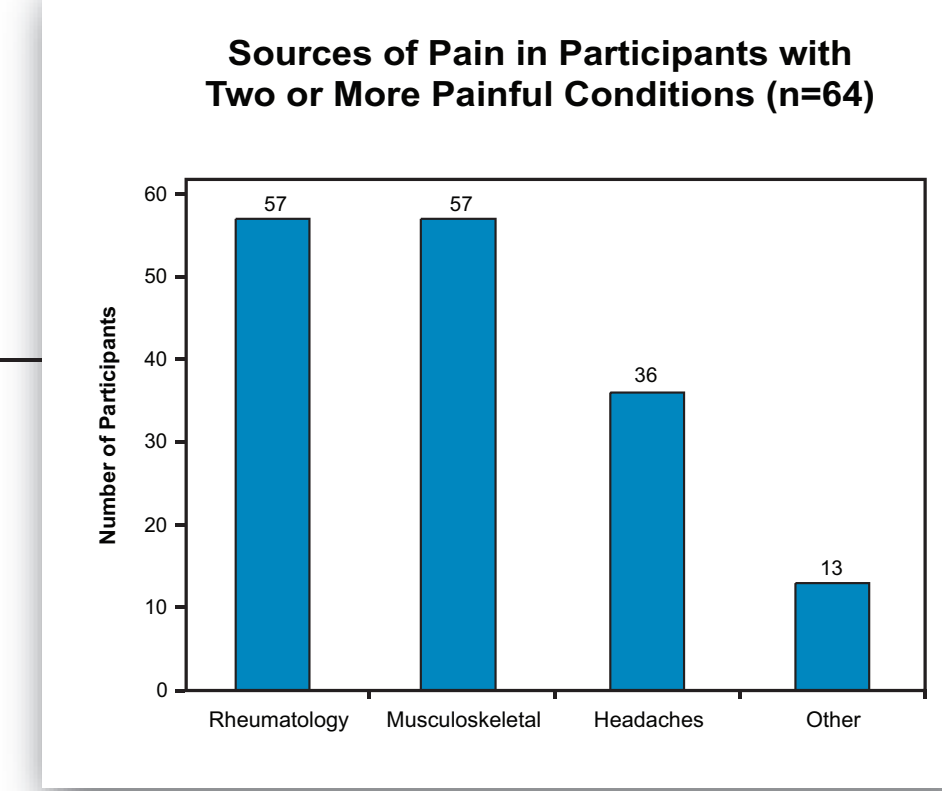
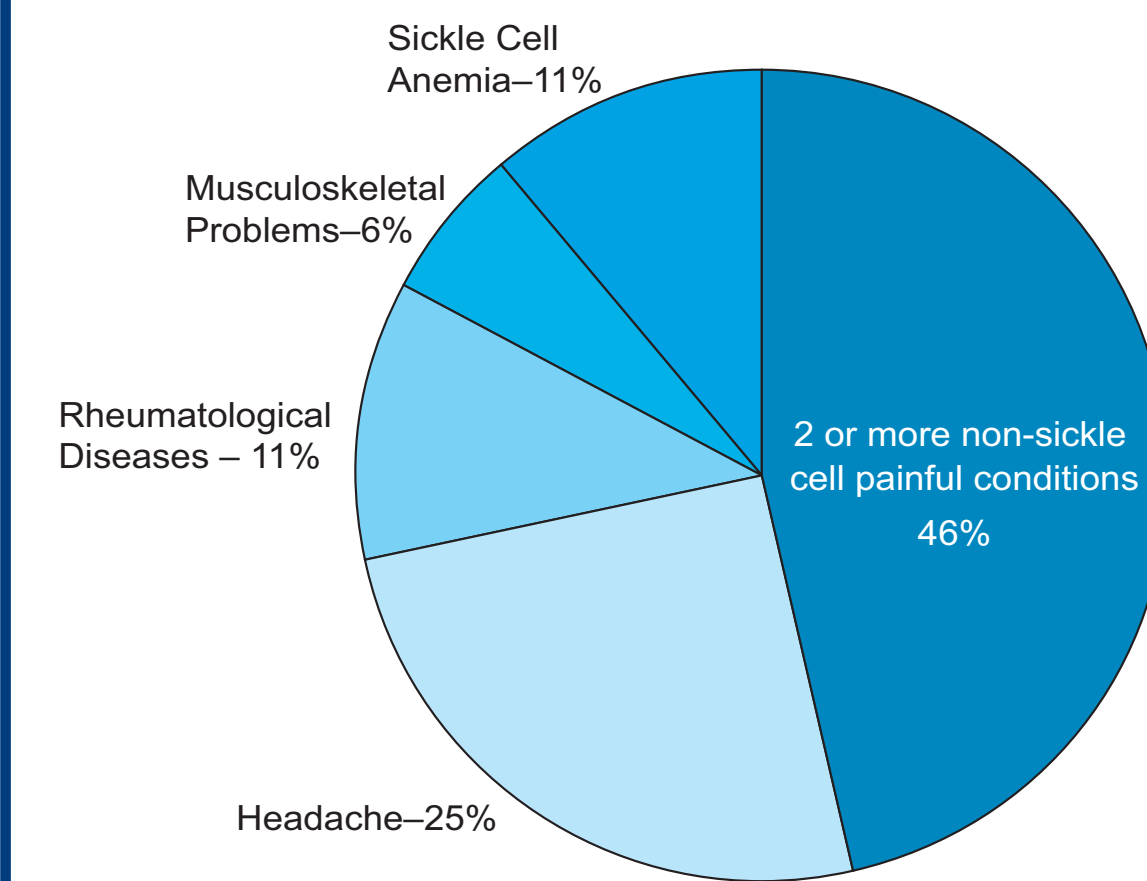
Demographics

A total of 161 participants completed the diary. Most were female (79%), caucasian (68%), and experienced at least 1 pain flare during the diary week (88%)

Gender	n	%
Females	127	79%
Males	34	21%
Ethnicity	n	%
Caucasian	106	68%
African American	45	29%
Hispanic	4	3%
Asian	1	1%
Other	1	1%
At Least 1 Pain Flare During Diary Week	n	%
Yes	141	88%
No	15	9%

Sources of Pain Among Participants

Enrollment By Pain Source (n=141)



Pain Flares During Diary Week

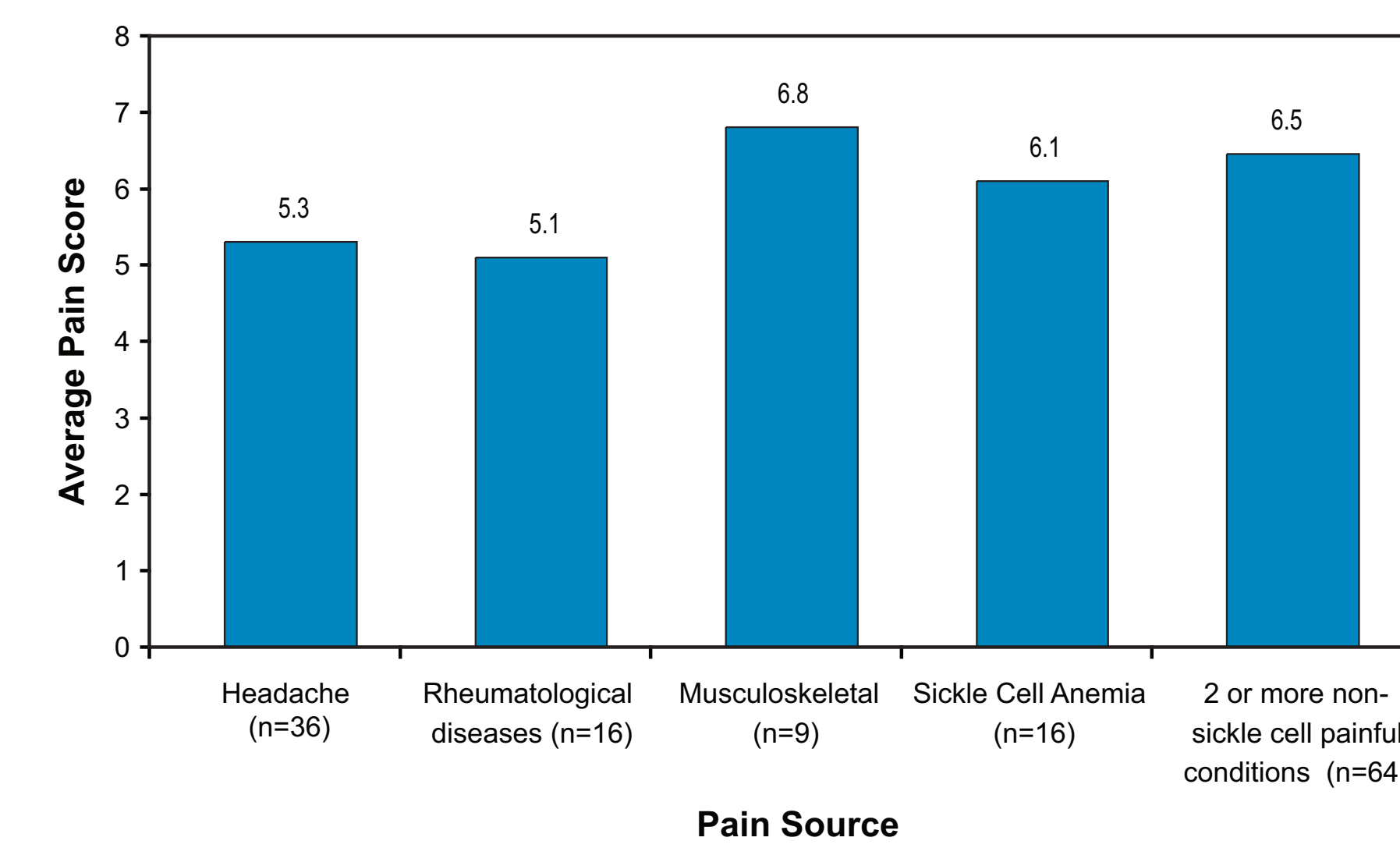
The cohort experienced a total of 2559 pain flares (mean per patient per week=18.1)

	Per Patient				All Patients (n=141)
	Mean	Median	SD	Range	Sum
Total Pain Flares	18.1	14.0	13.8	1.0-71.0	2559.0
Pain Flares Per Day	2.8	2.1	2.2	0.1-11.7	397.0

Baseline Pain Score By Pain Source

The mean pain levels were 5.3 for headache, 5.1 for rheumatological diseases, 6.8 for musculoskeletal problems, 6.1 for sickle cell anemia, and 6.5 for those with 2 or more painful conditions

Mean Pain Score During Diary Week by Pain Source (n=141)^{*}

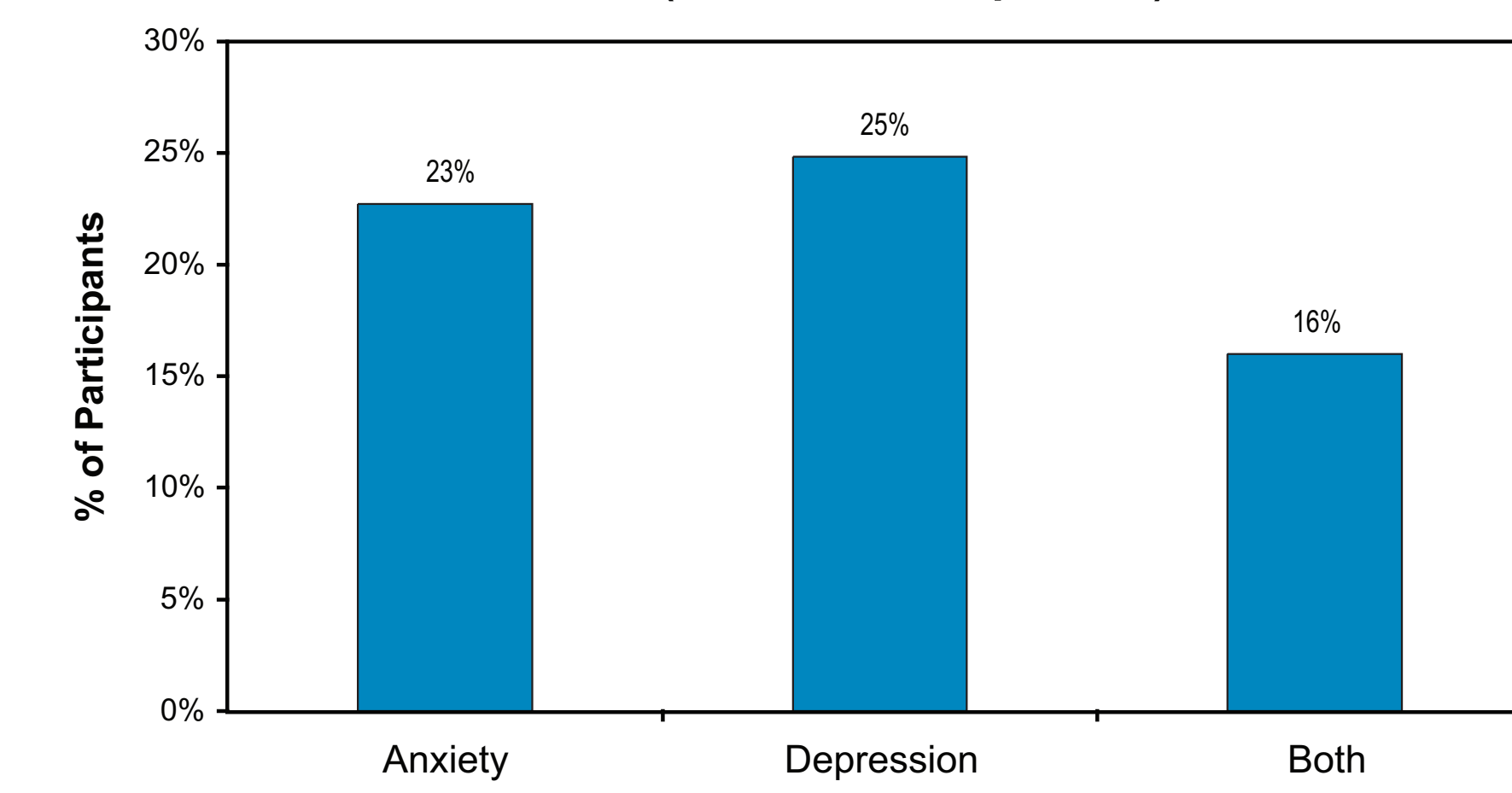


^{*} Pain scores based on 10-point scale with 0 described as "No Pain" and 10 described as the "Worst Pain Imaginable"

Anxiety and Depression

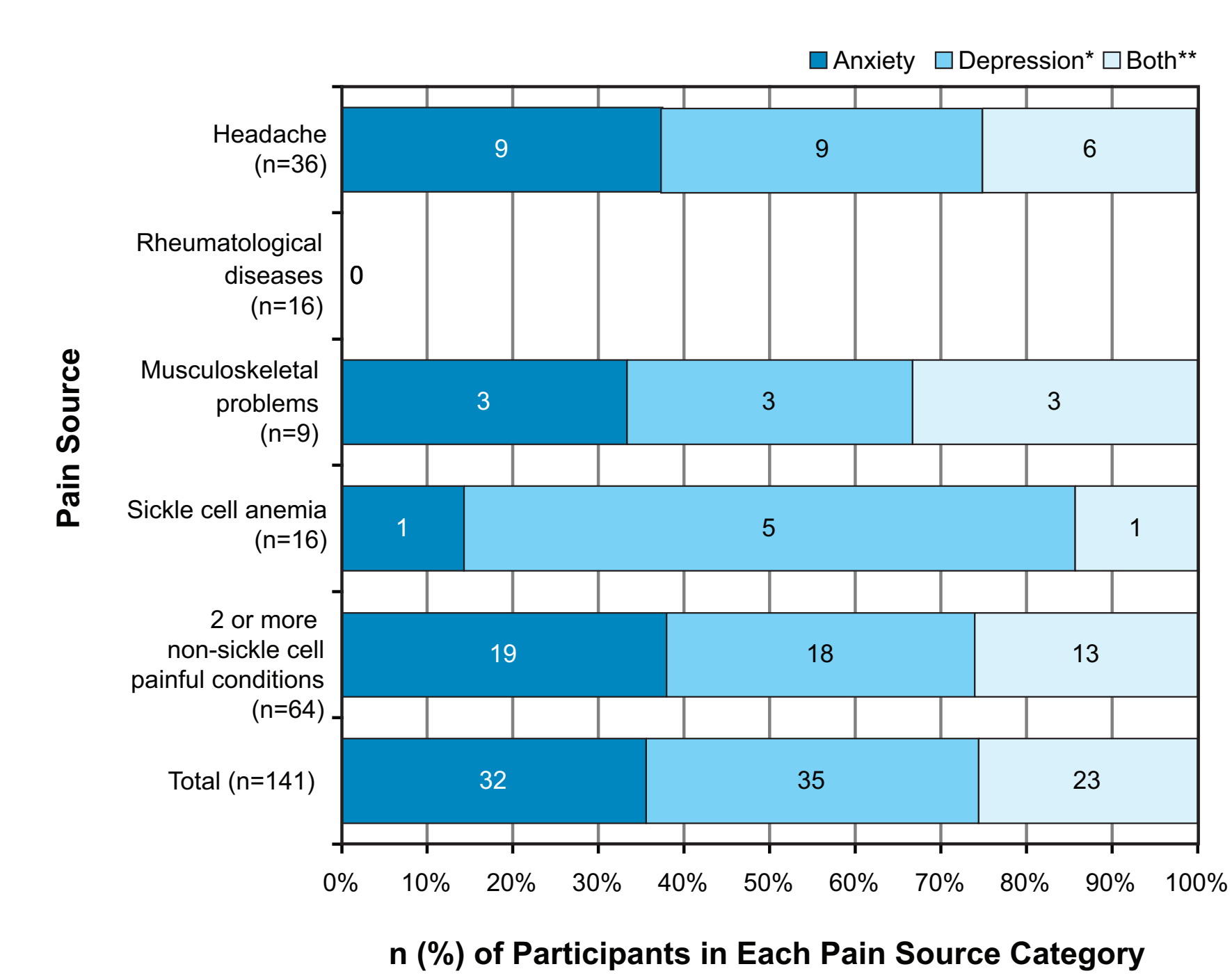
Anxiety and depression were noted to be prevalent (23% reported anxiety, 25% reported depression, 16% reported both)

Prevalence of Anxiety and/or Depression (n=141; Self Reported^{*})



^{*} Participants were asked to report which medical conditions they had "based on a diagnosis by a medical doctor."

Anxiety and Depression by Pain Source (n=141)



^{*}p<0.05 for depression; ^{**}p<0.05 for both anxiety and depression

Most Commonly Reported Prescription Medications for Pain (n=141)^{*}

Prescription Medication	Number of Participants (n=141)	Percent of Participants (n=141)	Percent of Scripts (n=291)
Oxycodone/Acetaminophen	26	18.4	8.93
Naproxen	20	14.2	6.87
Hydrocodone/Acetaminophen	19	13.5	6.53
Tramadol	19	13.5	6.53
Gabapentin	16	11.3	5.5
Topiramate	11	7.8	3.78
Acetaminophen/Codeine	8	5.7	2.75
Cyclobenzaprine	8	5.7	2.75
Hydromorphone	8	5.7	2.75
Morphine	8	5.7	2.75
Nortriptyline	8	5.7	2.75

^{*}Figure shows prescription pain medications taken by at least 5% of participants, at baseline

Alternative Methods Used to Relieve and/or Cope with Pain (at baseline; n=141)

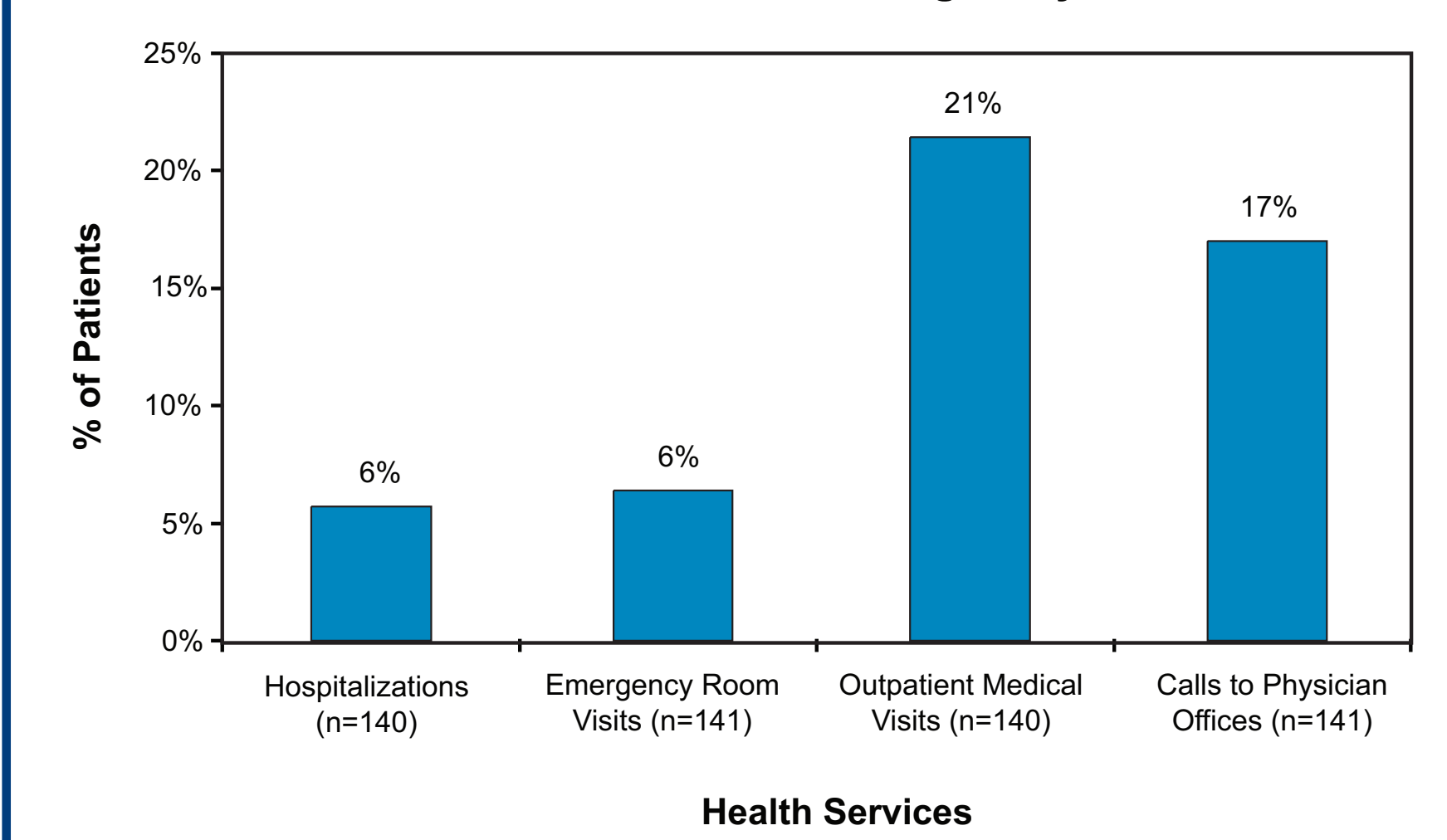
Method	n	%
Rest	111	78.2
Change Position	87	61.3
Hot or Cold Packs	86	60.5
Exercise	60	42.2
Prayer	58	40.8
Massage	54	38.0
Relaxation Technique	31	21.8
Physical Therapy	29	20.4
Epidural	29	20.4
Talked to Someone	29	20.4
Psychological Counseling	24	16.9
TENS [*]	16	11.3
Herbal Remedies	10	7.1
Creative Technique (art or music therapy)	9	6.4
Acupuncture	6	4.3

^{*}Transcutaneous Electrical Nerve Stimulation

Healthcare Resource Utilization

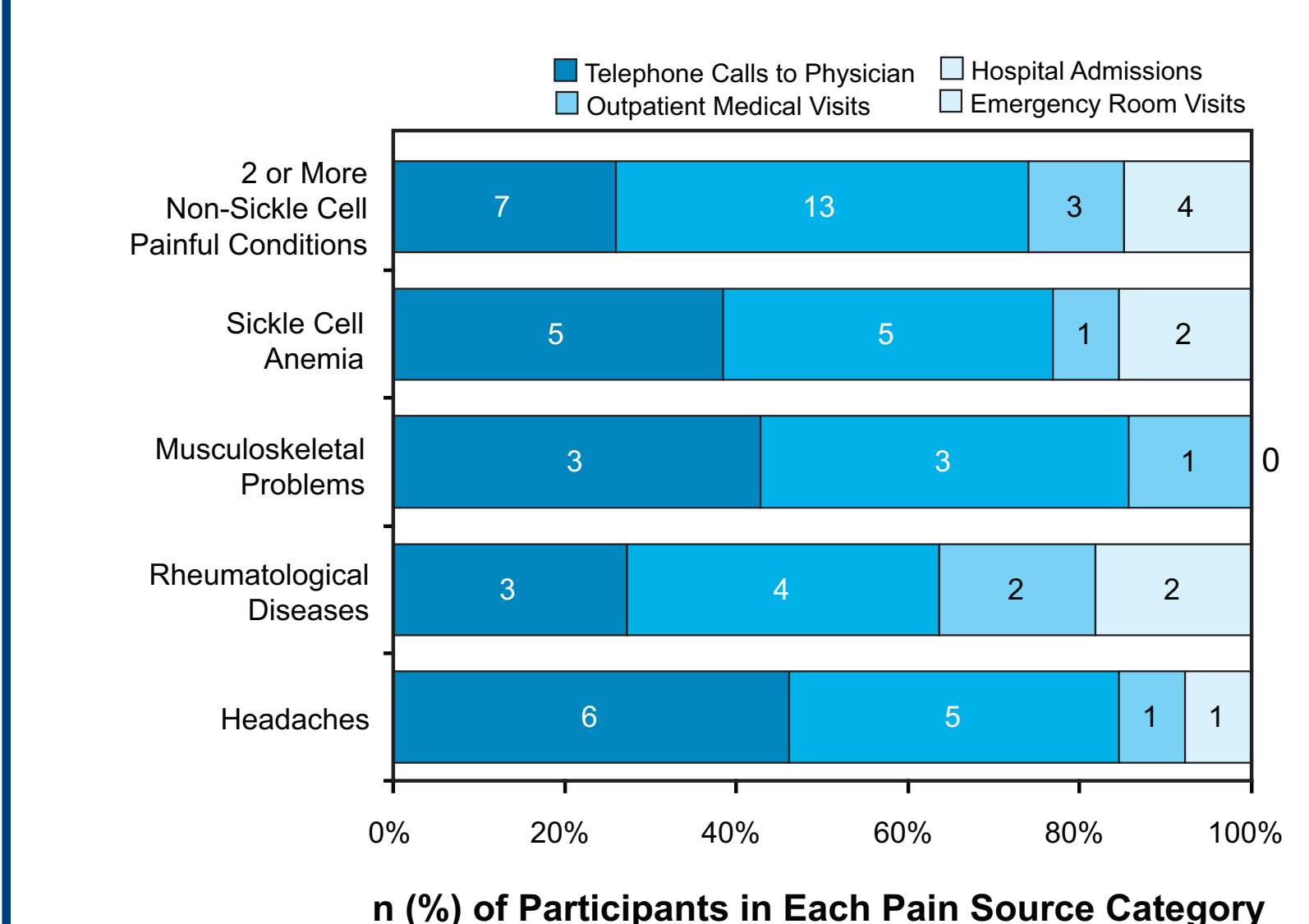
During the diary week, pain flares resulted in 8 hospitalizations, 9 emergency room visits, 30 outpatient medical visits, and 24 calls to physician offices

Healthcare Resource Utilization Due to Pain Flares During Diary Week



Healthcare Resource Utilization By Pain Source

Healthcare Resource Utilization Due to Pain Flares During Diary Week, by Pain Source (n=142)



Work Productivity: Missed Hours

During the diary week, participants missed a total of 191 work hours and 905.3 hours of work "around the house" due to pain flares.

	Per Patient				All Patients
	Mean	Median	SD	Range	Sum
Work Loss (hours)	2.0	0.0	4.7	0.0-22.0	191.0
At Home Work Loss (hours)	6.9	4.0	8.0	0.0-39.0	905.3

Limitations

- Most participants experienced pain flares during the diary week, which precluded group testing between the pain flare vs. no pain flare groups
- Participants appear to have significant and persistent pain, limiting generalizability
- Analysis reflects only utilization, not costs

Conclusions

- Patients with chronic non-cancer pain frequently consume healthcare services to address pain flares
- Pain flares result in lost work time
- Relationship between treatment and economic outcomes (resource utilization and productivity), and the added burden of anxiety and depression in this population should be further examined